REMARKS/ARGUMENTS

The present application was originally filed with claims 1-24. Following entry of Applicants' election with traverse set forth herein, claims 11-24 are withdrawn pending rejoinder. Applicants reserve the right to pursue the non-elected subject matter in one or more divisional applications.

ELECTION WITH TRAVERSE

In response to the restriction requirement mailed November 06, 2006, Applicants elect, with traverse, Group I, claims 1-10 drawn to methods for inhibiting the growth of androgen-dependent tumor cells.

While the Applicants have made the required election, several aspects of the restriction requirement are believed improper and are respectfully traversed. To support a requirement for restriction there must be a serious search burden as evidenced by separate classification, status or field of search. MPEP 803. Further, the Office cites to MPEP 806.05(j) for the proposition that the inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a material different design mode of operation function or effect; (2) the inventions do not overlap in scope, i.e. are mutually exclusive; and (3) the inventions as claimed are not obvious variants. Applicants submit that with regard to the guidelines given by both MPEP 803 and 806.05(j), the Office has not met its burden and the restriction is improper.

The Office justifies the restriction between the claims of Groups I-IV on the grounds that the inventions identified by the Office, do not satisfy the requirements of 806.05(j). Applicants disagree for several reasons. First, applicants point out that this characterization of the claims is inapposite. Without expressing any opinion on the patentable distinctness of claims identified as Groups I-IV, applicants submit that the subject matter of the claims (1) are capable of use

together, are useful in treating, identifying and ameliorating androgen dependent diseases and further do not have a materially different design, mode of operation, function, or effect; (2) the inventions do overlap in scope and are not mutually exclusive. The claims of Groups I-IV are directed to uses of the same compounds that affect androgen dependent physiological responses. Thus, claims 1-10 (Group I) that recite methods for inhibiting the growth of androgen-dependent tumor cells are not mutually exclusive with respect to claims 11-16 (Group II) that are drawn to treating a patient with an androgen dependent disorder. Further, the use of the compositions recited in claims 17-18 and 22-24 (Group III) can also be used as a nutraceutical, as recited in claims 19-21 (Group IV), to alleviate symptoms identified with androgen dependent disorders. Applicants, therefore, posit that methods for inhibiting growth of androgen dependent tumor cells is an efficacious way of treating a patient with an androgen dependent disorder and that such treatment can be afforded as a nutraceutical. Thus, the claims of Groups I-IV do overlap and are not mutually exclusive. Thus, the restriction is overcome and should be withdrawn.

Further, applicant's point out that MPEP 803 states that restriction is not proper if there is no serious burden placed on the Office in searching the entire application. The fact that the Office has classified all the claims as belonging to class 514, subclass 456 indicates that a search of all the claims would be coextensive with the other.

Specifically, while the Office states that the claims of Group I and Group II do not overlap, the Office points out that the claims of Group I are a logical extension of Group II because Group II recites a method of treating an androgen dependent disorder which necessarily occurs at a cellular level and which can be identified and quantified when directed at androgen-dependent tumor cells. Thus, a search of the claims of Group II necessarily would encompass a search of the claims of Group I. For example, the Office states that the method of Group I

(claims 1-10) is drawn to inhibiting androgen-dependent tumor cells whereas the method of Group II (claims 11-16) is drawn to treating a patient with an androgen-dependent disorder. The Office states that Group II claims are inherently an *in vivo* method while the Group I claims *can* be in vitro (applicant's also point out that the claims of Group I can also be *in vivo*). Because of these supposed differences, the Office states that the patient populations of Group I and II are distinct and would require a different search. However, in both cases, the claims require the use of the inventive compounds to ameliorate an androgen dependent disorder. While in claim 1, the disorder is identified as occurring at the cellular level (e.g. in tumor cells); in claim 11, the disorder occurs at the receptor level. The receptor is inherently on the cell surface. In both instances, the use of the method according to the claims requires the search of cells which respond to androgen. Without expressing any opinion as to the patentable distinctness of the two groups, Applicant's submit that the Office cannot perform a search of the claims of either group I or II without performing a search of the other. While the Office states that the claims of Group II include the treatment of any androgen-dependent disorder and Group I is only directed to androgen-dependent tumor cells the Office is still required to search for the efficacy of the claimed compounds in androgen dependent cells. In this context, claims 1-10 simply cannot be searched without searching claims 11-16. Finally, this interpretation of the claims is reinforced by pointing out that the Office itself has classified the claim of Groups I and II in class 514, subclass 456. Therefore, in any case, a search of the two groups would be coextensive. Thus, this aspect of the restriction between Group I and Group II is overcome and should be withdrawn.

The Office states that the claims of Groups III and I-II/IV are related as product and process of use as is shown by the fact that "the claimed (sic) could be used as antioxidants as

evidenced by the prior use of such compounds." However, applicant's point out that, as reinforced by the Office's own classification, the compositions recited in the claims of Group III are the same as those of Groups I, II and IV and would still have to be searched. Thus, the search of the claims is coextensive and does not represent and undue burden on the Office. Therefore, this aspect of the restriction requirement is overcome and should be withdrawn.

The Office further, states that the inventions of Groups IV and I/II are unrelated. The Office states that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation and effects. The Office states that these groups have different designs and modes of operation with the claims of Group IV drawn to a method of providing 'nutritional' benefits to a patient whereas the claims of Groups I and II are drawn to the treatment of an androgen-dependent condition and that, therefore, the search for treating an androgen dependent conditions would be different than the search required for methods of providing nutraceutical benefits. The Office then concludes that the patient populations are different in the two groups. This characterization is unfounded. First, applicants point out that the definition of nutraceutical is "[A] food or naturally occurring food supplement thought to have a beneficial effect on human health." (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000). Thus, the use of the compositions claimed is not for 'nutritional' purposes but to provide a beneficial effect on health. Such a beneficial effect would be found if, for example, the claimed composition were used to treat androgen dependent tumor cells or androgen dependent disorders. Therefore, the patient populations would not be two different groups but the same. Thus, this aspect of the restriction requirement is overcome and should be withdrawn.

CONCLUSION

In view of the election and arguments presented herein, Applicants respectfully submit that the Office has not made a *prima facie* case for restriction of the present claims. Applicants respectfully request reconsideration of the restriction requirement, rejoinder of the claims and examination on the merits of the rejoined claims. Applicants request that the Examiner telephone the undersigned in the event a telephone discussion would be helpful in advancing the prosecution of the present application. The Director is authorized to charge any additional fees or underpayment of fees regarding this response, including extensions for reply, to Deposit Account 07-1509.

Respectfully submitted,

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